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DOW CORNING CORPORATION CO1232
2200 W. SALZBURG ROAD
P.O. BOX 994
MIDLAND, MI 48686-0994

EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
12/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents.admin@dowcorning.com

Office Action Summary	Application No.	Applicant(s)	
	10/589,524	RAUL ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed May 12, 2009 are acknowledged and have been fully considered. Claims 1-18 are now pending. Claims 1, 10, 17, and 18 are amended; claims 14-18 are withdrawn. Claims 1-13 are now under consideration.

OBJECTIONS/REJECTIONS WITHDRAWN

The rejection of claims 1-5, 7, 8, and 10 under 35 U.S.C. 103(a) over ULMAN and PORTER is withdrawn in light of the claim amendments.

The rejection of claims 6, 9, and 11 under 35 U.S.C. 103(a) over ULMAN, PORTER, and KANIOS is withdrawn in light of the claim amendments.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claim 10 under 35 U.S.C. 112, 2nd paragraph is maintained, as discussed below.

The rejection of claims 12 and 13 under 35 U.S.C. 103(a) over ULMAN and PORTER is maintained, as discussed below.

The double patenting rejections of record have been maintained as no action regarding these rejections has been taken by applicants at this time.

Election/Restrictions

In the response of Aug. 28, 2009, applicants assert that chemical structures I and II are not independent and distinct since they are highly structurally related (see p. 2, 4th par.). Since applicants have essentially admitted that these structures are not patentably distinct, the election of species requirement between these structures is hereby withdrawn.

Claim Rejections - 35 USC § 112 (2nd Paragraph) (Maintained)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is indefinite in the recitation "less than about 20". This phrase is indefinite. See MPEP § 2173.05(b) which states, "In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for

indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that, based on the amendment to claim 10, they believe they have overcome the 112 2nd paragraph rejection (response, p. 11).

Contrary to applicants' assertion, the amendment to claim 10 does nothing to address the issue of the language "less than about 20", which remains in the claim. The claim is still indefinite for the reasons of record.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over ULMAN (U.S. 5,607,721, issued March 4, 1997) in view of PORTER (U.S. 5,785,978; Issued Jul. 28, 1998).

1. The teachings of Ulman and Porter are of record and are reiterated herein below. Regarding claims 12 and 13, it is noted that the term surfactant has not been defined in the instant specification. Therefore the term has been given its plain meaning and has been interpreted broadly. It is noted that the polyether is used *as* the surfactant in the instant specification and the polyether component is clearly synonymous with the recited surfactant (see paragraphs [0020] and [0030]). Thus, Ulman and Porter read on claims 12 and 13 based on the reasoning previously applied (see especially the rejection of claims 1-4 in the prior Office Action). Claims 12 and 13 are obvious over Ulman and Porter.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that they have demonstrated that claims 1-13 are not obvious over ULMAN and PORTER (response, p. 13).

Applicants have not demonstrated the alleged non-obviousness of the claims as discussed herein (see further discussion below). Additionally, applicants have not amended claims 12 and 13. The rejection of these claims is maintained for the reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 5,607,721

Claims 1-13 are non-provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,607,721 in view of Porter and Starch. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '721 claims renders obvious that of the instant claims. While the '721 claims are drawn

to a method of coating a silicone PSA onto a substrate, they encompass the step of mixing the instantly claimed adhesive elements, and step (i) of instant claim 1 is obvious as discussed above. Therefore, based on the reasoning applied above '721 and Porter render the instant claims obvious.

Claims 1-13 are directed to an invention not patentably distinct from claims 1-3 of commonly assigned 5,607,721. Specifically, the '721 claims render obvious the instant claims in combination with Porter.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 5,607,721, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that they have demonstrated that claims 1-13 are not obvious over ULMAN and PORTER, thus mooting the rejection (response, p. 13).

Applicants have not demonstrated the alleged non-obviousness of the claims as discussed herein. Thus, the double patenting rejection is not moot as asserted by applicants.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Objections

Claim 1 is objected to because of the following informalities: two distinct chemical structures are recited in the claim, but only one is given a label (i.e. (I)). The second chemical structure should also be labeled (e.g. as (II)) for clarity in the claim.

Claim 12 is objected to because its status identifier is incorrect. The claim is indicated as (Currently Amended), however, no amendment has been made. Applicants' cooperation in addressing this issue is requested to facilitate examination. The changes in any amended claim must be shown by strike-through (for deleted matter) or underlining (for added matter) with some exceptions. If an amendment has been made to the claim, the changes should be indicated by these markings. See MPEP 714, subsection C. See also CFR 1.121. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (1st Paragraph) (New Grounds of Rejection)

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed May 12, 2009 has introduced NEW MATTER into the claims. Amended claim 1 recites two chemical structures and limitations for the variable groups associated with these chemical structures. However, written description support is lacking for these chemical structures in the specification as filed.

The response did not point out where support for the amended claims could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Instant claims 1-11 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in amended claims 1-11, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the

limitations recited in present claims 1-11 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

It is noted that applicants cite U.S. patent 6,121,373 that does have support for the instantly recited structures. However, applicants have not incorporated this material by reference nor have they put forth a clear intent to do so. The attempt to incorporate subject matter into this application by reference to U.S. 6,121,373 is ineffective because the root words "incorporate" and "reference" have been omitted, see 37 CFR 1.57(b)(1). Any attempt to amend the specification to use the words "incorporate" and "reference", and thereby correct this deficiency will itself introduce new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 8, 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over ULMAN (U.S. 5,607,721, issued March 4, 1997) in view of STARCH (U.S. 6,121,373; Issued Sep. 19, 2000) and PORTER (U.S. 5,785,978; Issued Jul. 28, 1998).

2. Ulman discloses a pressure sensitive adhesive (PSA) composition comprising a siloxylated polyether and methods of making the same (abstract). Ulman teaches that due to the presence of the siloxylated polyether component, the adhesive compositions of the invention are especially suitable for delivering hydrophilic bioactive agents to a patient's skin (col. 7, lines 11-14; col. 7, lines 39-45). Ulman teaches that the adhesive compositions of the invention are prepared by mixing the PSA with the siloxylated polyether (i.e. elements (ii) and (iii) of instant claim 1) (col. 6, lines 24-29).

3. Ulman teaches that the siloxylated polyether can be *any silicone polymer that contains an alkyl wax and polyethylene oxide functionality*, such as those represented by the formulae at the top of col. 5. These formulae encompass dimethylsiloxy (wherein

R^2 is an alkyl radical having 1 carbon) and oxyalkylene functional siloxy (wherein A is a polyethylene oxide group) repeating units (col. 4, line 60 to col. 5, line 35). Ulman teaches that the R^2 radicals are preferably methyl (i.e. dimethylsiloxy repeating units) (col. 5, line 30). Ulman teaches that the number of repeating units in the polyether can be from 1-70 (col. 5, lines 53-55), encompassing the claimed degree of polymerization of less than about 20 (i.e. where there are less than about 20 repeating units per polymer chain). The high degree of similarity between the polyether structures of Ulman and those instantly claimed is noted, however, Ulman does not explicitly teach the specific silicon polyether structure instantly claimed. It is noted that this recitation is NEW MATTER as discussed *supra*.

4. Starch discloses compositions for delivering active agents to the skin (abstract; claim 1). Starch teaches the silicone polyethers of the exact chemical structure instantly claimed. One would be motivated to use the polyethers disclosed by Starch given Ulman's teaching that any polyether wax can be used in the invention, and given the high degree of structural similarity between Ulman's polyethers and those of Starch. In fact, it is only the oxyalkylene portion of the polyethers that differs between these structures, and this only by the position (i.e. branched vs. linear) of a single carbon in the second repeat unit of the oxyalkylene chain (see Ulman at col. 5, line 18). Thus, one of skill in the art would clearly have expected the two silicone polyethers to have similar properties. The MPEP states that "If such a species or subgenus is structurally similar to that claimed, its disclosure may provide a reason for one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the

reasonable expectation that structurally similar species usually have similar properties. See, e.g., *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *Deuel*, 51 F.3d at 1558, 34 USPQ2d at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.")." Additionally, Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious). See MPEP § 2144.08 and 2144.09. In light of Ulman's teachings and the similarity of the compounds disclosed in the prior art it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the silicone polyethers disclosed by Starch in the invention.

5. Furthermore, one would be motivated to use a lower molecular weight polyether (i.e. the lower range of Ulman teaching) because Ulman teaches that the siloxylated polyether functions to decrease the dynamic viscosity of the PSA. Since the ordinary artisan would recognize that degree of polymerization is also a measure of molecular weight, which correlates generally with viscosity (i.e. higher MW typically possess

greater viscosity), one would recognize the advantages of using a lower MW polyether, for example having a degree of polymerization of less than about 20.

6. Ulman teaches that the bioactive agent can be incorporated into the adhesive composition (col. 7, lines 11-14), but does not explicitly define at what stage of mixing that the bioactive agent is added. Therefore, Ulman does not explicitly teach element (i) of instant claim 1. Additionally, Ulman does not explicitly disclose suitable forms of the bioactive agent.

7. However, forming a first composition comprising a hydrophilic drug or excipient and the silicone polyether is one of only a small number of possibilities for the addition order of the components. In addition to the bioactive agent, the compositions of Ulman comprise only two other components; the PSA and the siloxylated polyether. Therefore, the artisan would have but three choices for the mixing order of the hydrophilic drug/excipient. The artisan could either choose to mix the hydrophilic drug/excipient with: 1) the silicone polyether prior to adding it to the adhesive; 2) the pressure sensitive adhesive prior to adding it to the polyether or 3) the mixture of the PSA and the silicone polyether. As such it would have been *prima facie* obvious to the ordinary artisan to mix the hydrophilic drug/excipient in any of these ways, and it would be routine for the artisan to do so to determine the best mode of dispersing the hydrophilic drug/excipient in the adhesive matrix. Nonetheless, the teachings of Ulman would have guided the artisan to the first of these three options. The distinctive feature of the Ulman compositions is the presence of the hydrophilic siloxylated polyether component (title; abstract), and it is clear from the teachings of Ulman that it is this component that

provides suitable compatibility of hydrophilic drugs/excipients (col. 7, lines 39-45). Further, Ulman teaches that prior art compositions without such a polyether component are inadequate for the delivery of hydrophilic drugs (col. 1, lines 62-64). Thus, the ordinary artisan would reasonably expect greater compatibility of the hydrophilic drug/excipient with the more hydrophilic polyether component (i.e. the well-known principle of like-dissolves-like), and would be motivated to form a pre-composition comprising the hydrophilic drug/excipient and the silicone polyether prior to mixing with the more hydrophobic PSA, which was known from the prior art to be incompatible with such hydrophilic components.

8. Regarding the limitation that the hydrophilic component be in powdered (i.e. solid) form, Ulman does not explicitly disclose suitable forms of the bioactive agent. Therefore, the ordinary artisan would have looked to the literature for guidance as to the form of the incorporated drug. The addition of powdered active agents to silicone pressure sensitive adhesives was well-known in the art at the time of the invention. For example, Porter discloses adhesives containing active ingredients for transdermal patches (abstract). Porter teaches that a preferable bioactive agent in the adhesive matrix is vitamin C (i.e. a hydrophilic bioactive agent) (col. 4, lines 16-17) and that the adhesive is preferably a pressure sensitive adhesive (col. 4, lines 28-29). Porter teaches that the active agents (e.g. vitamin C) are applied in powdered form (abstract), which is most preferred because the agents are more highly concentrated than in liquid form (col. 5, lines 36-42). Porter exemplifies silicone pressure sensitive adhesives containing powdered vitamin C in powdered form (Example 2.1-2.3).

9. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a hydrophilic drug (i.e. bioactive agent) in solid powdered form per the teachings of Porter. One would have been motivated to do so to produce an adhesive matrix with a highly concentrated active agent. Thus, claim 1 is obvious over Ulman, Starch, and Porter.

10. Regarding claims 2, 3, 7, and 8, it is noted that the term hydrophobic has not been defined in the instant specification. Therefore, the term has been given its ordinary meaning and has been interpreted broadly. PSAs are typically considered to be hydrophobic, as would be recognized by the ordinary artisan, and the PSA components described by Ulman are substantially the same as the PSA components of the instant application, which are deemed hydrophobic (see the abstract and paragraphs [0007] and [0010] of the instant application). For example, Ulman teaches that the use of silicone PSAs are preferred over other types of PSAs (col. 1, lines 28-29). The PSAs taught by Ulman comprise silicone resins of the MQ type that comprise $R_3SiO_{1/2}$ and SiO_4 units and comprise a hydroxyl-terminated (i.e. endblocked) polydiorganosiloxane fluid (abstract; col. 2, line 45-67). Ulman teaches that these fluids have a viscosity of 100 to 500,000 centipoise (it is noted that centipoise and centistokes are roughly equivalent, differing only by the specific gravity, which is close to one) (col. 3, lines 35-36). Thus, the adhesives of Ulman would be considered hydrophobic by an ordinary artisan and claims 2, 3, 7, and 8 are rendered obvious by Ulman and Porter.

11. Regarding claim 4, Ulman teaches applying the adhesive matrix to a substrate (abstract; col. 2, lines 30-31; col. 6, lines 28-29, 45, and line 63 to col. 7, line 14; claim 3). Thus, claim 4 is obvious over Ulman, Starch, and Porter.

12. Regarding claim 5, Ulman does not disclose the amounts of hydrophilic drug/excipient to be used in the invention. However, Ulman teaches the amount of drug released from the inventive composition can be controlled (col. 2, lines 1-2). It would be routine optimization for the ordinary artisan to adjust the amount of hydrophilic drug/excipient in the composition depending on the intended application of the adhesive, for example the particular patient and/or condition to be treated, the length of time for the treatment, and the particular drug used. Thus, claim 5 is obvious over Ulman, Starch, and Porter.

13. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a silicone polyether containing dimethylsiloxy and oxyalkylene repeating units and having a degree of polymerization less than about 20 per the teachings of Ulman. One would have been motivated to do so since Ulman teaches that such polyethers are preferred species of the polyether component and since they function to reduce the viscosity of the PSA, making it easier to spread. Thus, claim 10 is rendered obvious over Ulman, Starch, and Porter.

14. Regarding claims 12 and 13, it is noted that the term surfactant has not been defined in the instant specification. Therefore the term has been given its plain meaning and has been interpreted broadly. It is noted that the polyether is used *as* the surfactant in the instant specification and the polyether component is clearly synonymous with the

recited surfactant (see paragraphs [0020] and [0030]). Thus, Ulman and Porter read on claims 12 and 13 based on the reasoning applied above.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Porter does not teach the use of silicone polyethers (response, p. 12).

As recognized by applicants on p. 11 of the response, Porter is relied upon for the teaching of the conventionality of adding powdered drug components to adhesive compositions. Ulman teaches the use of silicone polyethers. In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Ulman teaches a polyether wax and assert that the instant silicone polyether is not a silicone polyether wax (response, p. 12).

Ulman defines a siloxylated polyether wax as any silicone polyether that contains and alkyl wax ($\geq C_6$) functionality and polyethylene oxide functionality (col. 4, lines 61-64). It is noted that the chemical structures recited by applicants embrace the definition of a siloxylated polyether wax set forth by Ulman. For instance, both chemical structures recited in claim 1 allow for alkyl wax (i.e. C = 6) functionalities. The fact that applicants do not use the term "wax" is immaterial. Applicants are invited to further clarify how their claimed polyethers are not waxes as defined by Ulman.

Applicants argue unexpected results and rely on an affidavit under CFR 1.132 in support of this assertion (response, p. 12).

The affidavit filed May 12, 2009 is insufficient to overcome the obviousness rejections herein for at least the following reasons. There are numerous problems with the affidavit. First, the micrographs provided do not show that the particle size of sample 4.1a is larger than that of sample 4.1b. On the contrary, the only full particles visible in these micrographs appear to be precisely the *same size*. Second, even if the micrographs were sufficient to show this property (which they do not), the affidavit neither explains why a decrease in size is an improvement, nor why such a decrease is unexpected. Third, applicants assert that a statistically significant difference in drug release "can be seen". This is not the case. A statistically significant difference is neither evident given the extraordinarily large standard deviations in Fig. 3, nor does the affidavit state that a statistically significant difference exists. Furthermore, even if such a difference was demonstrated, since Figs. 3 and 4 are not properly labeled (see the unlabeled legends at the bottom of both figures), it is impossible to tell what the data in the figures represents. It is also noted that Figs. 4 and 5 are missing from the affidavit. Moreover, Gerald K. Schalau states that *it is his opinion* that the release of the drug from the matrix is more consistent in one set of samples relative to another. However, Fig. 6 does not support this opinion as comparable rates of drug release were observed for both sample sets, as stated in paragraph 8 of the affidavit. Again, Fig. 6 is not labeled, so it is impossible to tell what the data actually represents. Finally, the scope of the affidavit is not commensurate with that of the instant claims. The affidavit does not

establish unexpected results for the claimed invention and is unpersuasive for removal of the obviousness rejections.

Claims 6, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulman in view of Starch and Porter as applied to claims 1-5, 7, 8, 10, 12, and 13 above, and further in view of KANIOS (U.S. 6,337,086; Jan. 8, 2002).

15. The teachings of Ulman, Starch, and Porter are presented *supra*. Additionally, Ulman teaches that silicone PSAs known in the art are typically solvent based adhesives, the solvents being employed primarily to reduce the PSAs viscosity prior to coating (col. 1, lines 14-19). Ulman teaches that the silicone resin can be dissolved in a solvent such as benzene, toluene, xylene, heptane, or linear or cyclic siloxanes, but does not disclose the amount of solvent in the adhesive matrix of the invention. Ulman does not teach the use of polydiorganosiloxane gums.

16. However, as noted by Ulman, solvent containing PSAs were well known in the art at the time of the invention. For instance, Kanios discloses transdermal drug delivery devices comprising a silicone PSA that comprises a silicone resin and a polydiorganosiloxane silicone fluid (abstract). Kanios teaches the use of an effective amount of an organic solvent such as, *inter alia*, benzene, toluene, xylene, or mixtures thereof, that is inert with respect to the other components of the PSA (col. 5, lines 13-15 and 50-54). Kanios teaches that it is preferred to have the PSA compositions in organic solvent solution wherein the organic solvent comprises from 30-70 weight percent of the total mixture of PSA components (col. 11, lines 33-38).

17. Kanios further teaches the use of hydroxyl-endblocked polydiorganosiloxane gums, which are polydiorganosiloxanes having viscosities in excess of 1,000,000 cP (col. 6, lines 51-54). Kanios teaches that blending endblocked silicone resins with polydiorganosiloxane gums results in a PSA composition having minimal hydroxyl radical content, which can be useful to prepare PSA films for transdermal drug delivery (col. 14, line 62 to col. 15, line 12). Kanios teaches that the use of solvents is often necessary when using gums in the PSAs (col. 10, lines 41-46). Since Ulman does not disclose suitable amounts of solvent in the PSA, the ordinary artisan would look to the literature for guidance on this parameter, and would be motivated to use values known in the art for similar PSA compositions, such as those taught by Kanios. Thus, claims 6, 9, and 11 are rendered obvious over Ulman, Starch, Porter, and Kanios.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the claimed invention is not obvious over Ulman and Porter based on the alleged unexpected results (response, p. 13).

As discussed supra, applicants have not demonstrated nonobviousness nor have they demonstrated unexpected results. The claims are properly rejected over Ulman, Starch, Porter, and Kanios.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235,

1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Summary/Conclusion

Claims 1 and 12 are objected to; claims 1-13 are rejected.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Kevin S Orwig/

/David J Blanchard/
Primary Examiner, Art Unit 1643